

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Letters Patent of:  
Tomohiro MATSUSHIMA et al.

Patent No.: 7,612,208 B2

Issued: November 3, 2009

For: CRYSTALLINE FORM OF THE SALT OF 4-  
(3-CHLORO-4-  
(CYCLOPROPYLAMINOCARBONYL)AMIN  
OPHENOXY)-7-METHOXY-6-  
QUINOLINECARBOXAMIDE OR THE  
SOLVATE OF THE SALT AND A PROCESS  
FOR PREPARING THE SAME

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**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**  
**UNDER 37 C.F.R. § 1.705 (d)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Patentee notes that the **485** days of Patent Term Adjustment (PTA) as indicated on the Issue Notification mailed on October 14, 2009, as well as shown on the cover of the Letters Patent itself, for the above-captioned patent disagrees with Patentee's own calculation of PTA. Thus, the PTA for this patent should be re-calculated.

Additionally, Patentee received the attached USPTO Decision on the Request for Reconsideration of Patent Term Adjustment filed on May 14, 2009. The Request for Reconsideration was dismissed as being premature. Therefore, the Patentee is now submitting a

Request for Reconsideration of PTA under 37 CFR § 1.705(d)

timely Request for Reconsideration of PTA. Pursuant to CFR § 1.705 (d), the Patentee hereby requests reconsideration of the patent term adjustment indicated on the Issue Notification for Patent No. 7,613,342 (Exhibit 1). Specifically, while the Issue Notification indicates a patent term adjustment of 485 days, Patentee submits that the patent term adjustment should correctly be 637 days.

### STATEMENT OF FACTS

1. The Issue Notification issued in this case on October 14, 2009, indicated that the Patent Term Adjustment to date was 485 days.
2. The U.S. Patent and Trademark Office's Patent Term Adjustment History, as indicated in the Patent Application Information Retrieval (PAIR) system indicates a Patent Term Adjustment due to 0 days of applicant delays and 485 days of USPTO delays (see Exhibit 2).
3. In accordance with the recent District Court decision in *Wyeth et al. v. Dudas*, 580 FSupp2d 138, 88 USPQ2d 1538 (D.D.C. 2008), the correct Patent Term Adjustment should be 453 days of initial prosecution delay (14 months PTO first Office Action), plus 32 days (4-month PTO issue of patent after Issue Fee was paid), plus 189 days for the failure of the USPTO to issue a patent within three (3) years of the actual filing date of the application (37 C.F.R. § 1.702(b)); minus 5 days of applicant's delay, for a total of 637 days of Patent Term Adjustment.
4. Accordingly, Patentee hereby requests that the U.S. Patent and Trademark Office correct the calculation of the Patent Term Adjustment for the above-identified patent to 637 days.

**COMPLIANCE WITH REQUIREMENTS OF****37 CFR § 1.705 (b)(1) AND (2)**

5. A statement of facts is presented above, detailing the relevant dates and the correct patent term adjustment.
6. The present patent is not subject to any Terminal Disclaimer or any expiration date specified in a Terminal Disclaimer (§ 1.705(b)(2)(iii)).
7. There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the above-identified application (37 C.F.R. § 1.705(iv)(B)).

Furthermore, the May 14, 2009 USPTO Decision explains that the first Request was premature since the patent has not actually issued yet, and thus any delay cannot yet be determined. However, the filed Request was not directly solely to the USPTO's failure to issue a patent within 3 years, as the Request is in partial response to the District Court decision in *Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (D.D.C. September 30, 2008).

More specifically, 35 U.S.C. § 154(b)(1)(A) defines three types of "**A delay**". Two of those three types of the **A delay** include the USPTO's failure to **(i)** initially act on the application within **14 months** after filing or national stage entry date (e.g., issuance of an Office Action) as well as **(ii)** the USPTO's failure to issue the patent within **4 months** of the date the issue fee was paid and all outstanding requirements were satisfied.

Also, 35 U.S.C. § 154(b)(1)(B) defines a "**B delay**" as the USPTO's failure to issue a patent within **3 years** of the actual filing date of the application in the U.S.

Patentee's first Request, and the present Request, are both directed to how the USPTO has been "double counting" – giving the longer of either the **A delay** or the **B delay** when there is overlap. Patentee is entitled to any delay under 35 U.S.C. § 154(b)(1)(A) as well as under § 154(b)(2)(B) (and § 154(b)(1)(C) or "**C delay**"). By filing these Requests, Patentee is contesting the practice that any **A delay** would apply to both time periods (i) and (ii) as mentioned above and should both be counted.

Furthermore, the provisions 37 C.F.R. § 1.705(d) specify that estoppel would apply if Patentee did not traverse the potential double counting by the USPTO before the issue fee was paid:

(d) If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Any request for reconsideration under this section that raises issues that were raised, *or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.* (Emphasis added.)

Thus, the first Request pursuant to 37 C.F.R. § 1.705(b) was filed.

The present Request under 37 C.F.R. § 1.705(d) is also being filed to prevent such double counting. Specifically, the **189** days as a type of **B delay** as well as the **453** days and **32** days as types of **A delays** should both count towards PTA, and not just one of the two. Patentee notes that there are 32 days of overlap between the 4-month issue rule and the 3-year grant rule. It is also worth noting that the lower of the two types of delay is calculated in the USPTO determination of PTA ( $32 + 453 = 485$ ) instead of the 189 days of delay. This is also erroneous.

In any event, Patentee requests reconsideration of the PTA.

### CONCLUSION

The USPTO is requested to correctly indicate that U.S. Patent No. 7,613,342 is entitled to 637 days (if not more) of Patent Term Adjustment.

### PAYMENT OF FEES

Patentee notes that the \$200.00 fee set forth in 37 C.F.R. § 1.18(e) for consideration of the application for patent term adjustment under 1.705(d) is herein submitted.

If necessary, the Commissioner is hereby authorized to charge the amount of \$200.00 to Deposit Account No. 02-2448 for consideration of this request as required by 37 C.F.R. 1.18(e).

Dated: December 24, 2009

Respectfully submitted,

By

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Registration No.: 32,881

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#### Attachments:

Decision on the Request for Reconsideration of PTA

Exhibit 1 -- Issue Notification

Exhibit 2 -- Patent Term Adjustment History From PAIR



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
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PO BOX 747  
FALLS CHURCH VA 22040-0747

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SEP 29 2009

OFFICE OF PETITIONS

In re Application of :  
Matsushima et al. :  
Application No. 10/577531 : ON REQUEST FOR  
Filing or 371(c) Date: 04/28/2006 : RECONSIDERATION OF  
Attorney Docket No. : PATENT TERM ADJUSTMENT  
1056-0138PUS1 :

This is in response to the REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(b), filed May 14, 2009. Applicant submits that the correct patent term adjustment to be indicated on the patent is 586 days, not 453 days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicant requests this correction solely on the basis that the Office will take in excess of three years to issue this patent.

As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is **DISMISSED as PREMATURE.**

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, applicant is

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90 2828

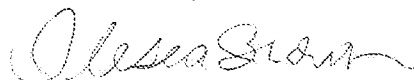
advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. However, as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicant must timely file an application for patent term adjustment prior to the payment of the issue fee<sup>1</sup>.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e) for consideration of the application for patent term adjustment under 37 CFR 1.705(b).

Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d) and must include payment of the required fee under 37 CFR 1.18(e).

The Office of Data Management has been advised of this decision. This application is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries specific to this decision should be directed to Attorney Derek Woods at (571) 272-3232.



Alesia Brown  
Senior Petitions Attorney  
Office of Petitions  
Office of the Deputy Commissioner  
for Patent Examination Policy

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<sup>1</sup> For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the §1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.



# UNITED STATES PATENT AND TRADEMARK OFFICE



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United States Patent and Trademark Office  
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,531	11/03/2009	7612208	1056-0138PUS1	9835

2292 7590 10/14/2009  
BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

## ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

### **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)** (application filed on or after May 29, 2000)

The Patent Term Adjustment is 485 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

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10/577,531

CRYSTALLINE FORM OF THE SALT OF 4-(3-CHLORO-4-(CYCLOPROPYLAMINOCARBONYLAMINO)PHENOXY)-7-METHOXY-6-QUINOLINECARBOXAMIDE OR THE SOLVATE OF THE SALT AND A PROCESS FOR PREPARING THE SAME



Select New Case	Application Data	Transaction History	Image File Wrappers	Patent Term Adjustments	Continuity Data	Foreign Priority	Fees	Published Documents	Address & Attorney/Agent	Assignments	Display References
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**Patent Term Adjustment**

Filing or 371(c) Date:	04-28-2006	USPTO Delay (PTO) Delay (days):	485
Issue Date of Patent:	11-03-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	0
Post-Issue Petitions (days):	+0	Total Patent Term Adjustment (days):	485
USPTO Adjustment (days):	+0	<a href="#">Explanation Of Calculations</a>	

**Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
10-14-2009	PTA 36 Months		
11-03-2009	Patent Issue Date Used in PTA Calculation	32	
10-02-2009	Dispatch to FDC	*	
10-02-2009	Email Notification	*	
09-29-2009	Mail-Petition Decision - Dismissed	*	
09-28-2009	Petition Decision - Dismissed	*	
06-03-2009	Application Is Considered Ready for Issue	*	
06-02-2009	Issue Fee Payment Verified	*	
06-02-2009	Issue Fee Payment Received		
05-14-2009	Petition Entered		
05-19-2009	Email Notification		
05-19-2009	Mail PUB Notice of non-compliant IDS		
05-15-2009	PUB Notice of non-compliant IDS		
05-14-2009	Information Disclosure Statement considered		
05-14-2009	Information Disclosure Statement (IDS) Filed		
03-03-2009	Mail Notice of Allowance		
02-26-2009	Notice of Allowance Data Verification Completed		
02-26-2009	Case Docketed to Examiner in GAU		
02-26-2009	Document Verification		
12-19-2008	Information Disclosure Statement considered		
12-19-2008	Reference capture on IDS		
12-19-2008	Information Disclosure Statement (IDS) Filed		
01-22-2009	Date Forwarded to Examiner		
12-19-2008	Response after Non-Final Action		
12-19-2008	Information Disclosure Statement (IDS) Filed		
09-23-2008	Electronic Review		
09-23-2008	Email Notification		
09-23-2008	Mail Non-Final Rejection	453	
09-18-2008	Non-Final Rejection	*	
03-20-2007	Information Disclosure Statement considered	*	
09-26-2006	Information Disclosure Statement considered	*	
04-28-2006	Information Disclosure Statement considered	*	
10-10-2007	Case Docketed to Examiner in GAU	*	
07-07-2007	IFW TSS Processing by Tech Center Complete	*	
03-20-2007	Information Disclosure Statement (IDS) Filed	*	
03-20-2007	Substitute Specification Filed	*	

03-20-2007	Preliminary Amendment	✦
09-26-2006	Information Disclosure Statement (IDS) Filed	✦
04-28-2006	Request for Foreign Priority (Priority Papers May Be Included)	✦
04-28-2006	Reference capture on IDS	✦
04-28-2007	Information Disclosure Statement (IDS) Filed	✦
04-28-2006	Preliminary Amendment	✦
04-28-2006	Information Disclosure Statement (IDS) Filed	✦
09-26-2006	Information Disclosure Statement (IDS) Filed	✦
03-20-2007	Information Disclosure Statement (IDS) Filed	✦
05-05-2007	Electronic Review	✦
05-04-2007	Email Notification	✦
04-28-2006	371 Completion Date	✦
04-24-2007	Application Dispatched from OIPE	✦
04-24-2007	Notice of DO/EO Acceptance Mailed	✦
04-10-2007	Electronic Review	✦
04-09-2007	Email Notification	✦
04-09-2007	PG-Pub Issue Notification	✦
05-25-2006	Cleared by OIPE CSR	✦
04-28-2006	Initial Exam Team nn	✦

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